

REMARKS

I. Status Summary

Claims 1-4, 7-10, 58-60, and 69-71 are pending in the subject U.S. patent application and have been examined by the United States Patent and Trademark Office (hereinafter "the Patent Office") in a Final Official Action dated February 22, 2011 (hereinafter the "Final Official Action"). Claims 61-68 have been withdrawn as being directed to non-elected subject matter. Claims 1-4, 7-10, 58-60, and 69-71 presently stand rejected.

The Patent Office has presented a claim general objection that appears to be a suggestion for alternative claim language for applicants to consider.

The restriction of claims 61-68 has been maintained upon the contention that the claims are directed to non-elected subject matter.

The Patent Office has rejected claims 70 and 71 under 35 U.S.C. § 112, first paragraph, upon the contention that the claims include new matter.

The Patent Office has rejected claims 1-4, 7-10, 69, and 70 under the enablement provision of 35 U.S.C. § 112, first paragraph.

The Patent Office has rejected claims 1-4, 7-10, and 58-60 under 35 U.S.C. § 112, second paragraph, upon the contention that the claims are indefinite.

Claims 59, 62-67, and 70 have been canceled without prejudice.

Claims 1, 3, 4, 7, 8, 58, 60, 61, and 69-71 have been amended. Support for the amendments can be found throughout the specification as filed, including particularly in the original claims (see e.g., amendments to claims 3 and 60 to correct dependencies to claims 2 and 58, respectively). Additional support can be found as follows:

Claims	Element and Support
1, 7, and 69	<ul style="list-style-type: none"><li>• immunizing a female bird with an immunogen composition comprising an immunogenic epitope of a DAZL polypeptide (Example 1, page 51, and Pages 53-54, Table 1, in view of definition of "immunogenic epitope on page 25, lines 29-31);</li><li>• obtaining an egg comprising an embryo from the female bird (Example 2, page 54, line 3);</li></ul>

	<ul style="list-style-type: none"><li>• wherein as a result of immunizing the female bird, the embryo has a decreased number of primordial germ cells (Page 35, line 13, through page 36, line 2);</li></ul>
58, 61, 69, and 71	<ul style="list-style-type: none"><li>• Immunizing with immunogenic epitopes of both a DAZL polypeptide and a VASA polypeptide (Pages 53-54, Table 1).</li></ul>

With respect to the amendment to claims 4 and 60, these amendments are formal in nature to harmonize the recited terminology with that employed in claims 1 and 58, respectively. Thus, no new matter has been added by the amendments to the claims.

New claims 72-75 have been added. Support for the new claims can be found in the specification as filed, including particularly at pages 53-54 in Table 1 in view of page 25, lines 19-24. Thus, no new matter has been added by the inclusion of the new claims.

Reconsideration of the application as amended and in view of the remarks presented herein below is respectfully requested.

## II. Discussion of Withdrawn Claims and Objections to the Claims

The restriction of claims 61-68 has been maintained upon the contention that the claims are directed to non-elected subject matter. Particularly, the Patent Office alleges that claims 61-68 are directed to administering two antigens whereas applicants have made a species election of administering DAZL. The Patent Office also maintains that claims 63-68 are drawn to producing a chimeric avian relevant to invention Groups III and IV of the Restriction Requirement sent May 16, 2007, but not Applicants' elected Group II. The Patent Office now contends that new claims 69-71 also encompass administering two antigens and that they would thus be examined as they relate to administering the elected antigen species, DAZL.

Turning first the withdrawal of claims 63-68, claims 63-67 have been canceled without prejudice. As such, it is believed that the withdrawal of claims 63-67 is now moot.

With respect to claim 68, however, applicants respectfully submit that the Patent Office has presented no basis upon which to assert that this claim is directed to producing a chimeric avian. It is noted that claim 68 depends directly from claim 58, and as such, relates to the method of claim 58 in which the avian embryo is incubated to hatch.

As such, applicants respectfully submit that it appears that the withdrawal of claim 68 is improper. Accordingly, applicants respectfully request that claim 68 be rejoined to the instant application and examined.

With respect to the withdrawal of claims 61 and 62, applicants respectfully note that claim 62 has been canceled without prejudice. Thus, the withdrawal of claim 62 is believed to be moot.

Turning now to the withdrawal of claim 61, applicants respectfully submit that the Restriction/Election Requirement of May 16, 2007 included a species election with respect to the "antigen associated with primordial germ cells". Thus, upon allowance of a generic claim, applicants are entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 C.F.R. § 1.141 (see *also* M.P.E.P. § 809.02). It is noted that the Restriction/Election Requirement of May 16, 2007 stated that "all the claims are generic (see page 4), In view of the remarks set forth hereinabove, which applicants believe place the pending claims into condition for allowance, applicants hereby seek rejoinder of additional species of "antigens associated with primordial germ cells".

Turning now to the objection to the claims, applicants respectfully submit that it appears that the Patent Office is suggesting alternative language for the independent claims. With this in mind, applicants have amended claims 1, 7, 58, and 69 in a manner consistent with the suggestion presented on page 2 of the Final Official Action. Applicants further respectfully submit that support for each of the amendments to claims 1, 7, 58, and 69 can be found hereinabove. Thus, no new matter has been added by the amendments to the claims.

As a result of the amendments, applicants respectfully submit that the claim objections have been addressed, and respectfully request that they be withdrawn at this time.

III. Response to the New Matter Objection

The Patent Office rejected to claims 70 and 71 under 35 U.S.C. § 112, first paragraph, upon the contention that new matter has been introduced into the claims. The Patent Office contends that the range "50-200 µg" recited in claim 70 is unsupported by the specification. The Patent Office also asserts that support for claim 71 has not been provided and cannot be found in the specification.

After careful consideration of the rejections and the Patent Office's bases therefor, applicants respectfully traverse the rejections and submit the following remarks.

With respect to the rejection of claim 70, it is noted that the instant specification discloses primary immunizations of 100-200 µg and secondary immunizations of 50-100 µg. Thus, applicants respectfully submit that it is clear that one of ordinary skill in the art would understand after review of the specification that the specification as filed comprises immunizing with 50-100 µg under certain circumstances and 100-200 µg under other circumstances. As such, the specification as a whole describes exemplary immunizations comprising amounts that vary from 50 to 200 µg.

Nonetheless, in an effort to facilitate prosecution and without acquiescing to the Patent Office's assertions in support of the instant rejection, claim 70 has been canceled without prejudice. Thus, the instant rejection is believed to be moot. Applicants respectfully request that it be withdrawn at this time.

Turning now to the rejection of claim 71, applicants respectfully submit that the specification as filed clearly supports the subject matter of claim 71. As previously presented, claim 71 recited the method of claim 69, wherein the antigen is DAZL, and wherein the egg comprises antibodies that recognize DAZL in an amount sufficient to bind to DAZL on primordial germ cells of the embryo and decrease the number of primordial germ cells in the embryo. The antigen being DAZL is recited throughout the specification, including, for example, in Table 1. Thus, applicants respectfully submit that there is believed to be no basis for the Patent Office to assert that this aspect of claim 71 is not supported by the instant specification.

Turning now to the remaining language of claim 71, applicants respectfully submit that the phrase "wherein the egg comprising antibodies that recognize DAZL in

an amount sufficient to bind to DAZL on primordial germ cells of the embryo and decrease the number of primordial germ cells in the embryo is also discussed throughout the specification as filed. The Patent Office's attention is directed to page 35, lines 13-15, which state, "PGC numbers in the recipient bird are reduced as a result of the presence of maternal antibodies deposited in the yolk of the egg". Applicants respectfully submit that one of ordinary skill in the art would understand after review of the specification that the "maternal antibodies deposited in the yolk of the egg" are the antibodies that arise as a result of the immunization of the female bird with the antigen associated with PGC development (see *also* Specification at page 35, line 15, through page 36, line 2).

Nonetheless, in an effort to facilitate prosecution and without acquiescing to the Patent Office's assertions in support of the instant rejection, claim 71 has been amended to recite *inter alia* that the immunogen composition comprises an immunogenic epitope of a DAZL polypeptide. Support for this amendment can be found throughout the specification as filed, including particularly as set forth hereinabove. Thus, no new matter has been added by the amendment to claim 71.

As a result, it is believed that the instant rejection of claim 71 under 35 U.S.C. § 112, first paragraph has been addressed. Withdrawal of this rejection is respectfully requested. Allowance of the noted claim is also respectfully requested.

#### IV. Response to the Enablement Rejection

The Patent Office maintained a rejection of claims 1-4, 7-10, 69, and 70 under the enablement provision of 35 U.S.C. § 112, first paragraph. According to the Patent Office, the specification as filed does not enable using any "antigen associated with PGC development".

In an effort to facilitate prosecution and without acquiescing to the Patent Office's assertions in support of the instant rejection, claims 1, 7, 58, and 69 have been amended to delete the phrase at issue and recite particular immunogens. For example, the immunizing step comprises are recited as "immunizing a female bird with an immunogen composition comprising an immunogenic epitope of DAZL" in claims 1 and 7; and as "immunizing the female avian with an immunogen composition comprising an

immunogenic epitope of a DAZL polypeptide, an immunogenic epitope of a VASA polypeptide, or a combination thereof" in claims 58 and 69. Support for these amendments can be found throughout the specification as filed, particularly as set forth hereinabove. Thus, no new matter has been added.

In view of the amendments to claims 1, 7, 58, and 69, applicants respectfully submit that the instant rejection of claims 1-4, 7-10, 69, and 70 has been addressed. Claim 70 has been canceled, and thus the instant rejection is believed to be moot as to this claim. Applicants thus respectfully submit that claims 1-4, 7-10, and 69 are in condition for allowance, and respectfully solicit a Notice of Allowance to that effect.

V. Response to the Indefiniteness Rejections

The Patent Office has rejected claims 1-4, 7-10, and 58-60 under 35 U.S.C. § 112, second paragraph, upon the contention that the phrase "[S]ufficiently high concentration of antibodies that bind to the antigen expressed by an avian embryo present within the egg to thereby decrease endogenous PGC numbers [or development] in the avian embryo are decreased [inhibited]" appearing in claims 1, 7, and 58 is indefinite (see Final Official Action, page 8).

In an effort to facilitate prosecution and without acquiescing to the Patent Office's assertions in support of the instant rejection, the phrase at issue has been deleted from claims 1, 7, and 58.

Accordingly, it is believed that the instant rejection of claims 1-4, 7-10, and 58-60 under 35 U.S.C. § 112, second paragraph has been addressed. Claim 59 has been canceled, and thus the instant rejection is believed to be moot as to this claim. Applicants thus respectfully submit that claims 1-4, 7-10, 58, and 60 are in condition for allowance, and respectfully solicit a Notice of Allowance to that effect

VI. Request for Rejoinder of Species

Applicants respectfully submit that the Restriction/Election Requirement of May 16, 2007 included a species election with respect to the "antigen associated with primordial germ cells". Given that the specification as filed clearly provided for co-immunization with at least two peptides, applicants respectfully submit that in view of

the remarks presented herein above, it is believed that claims 1-4, 7-10, 58, 60, and 71 are in condition for allowance. Consequently, applicants respectfully submit that they are entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 C.F.R. § 1.141 (*see also* M.P.E.P. § 809.02).

As such, applicants respectfully request rejoinder of additional species of antigens associated with primordial germ cells. Applicants respectfully request that VASA be the next species to be examined, and that a combination of DAZL and VASA be the species that follows.

Accordingly, applicants respectfully request rejoinder of at least claim 61, and further respectfully request that the instant examination be extended to the full scope of the pending claims.

#### VII. Discussion of the New Claims

New claims 72-75 have been added. Support for the new claims can be found in the specification as filed, including particularly at pages 53-54 in Table 1 in view of page 25, lines 19-24. Thus, no new matter has been added by the inclusion of the new claims.

Applicants respectfully submit that claims 72-75 are believed to be in condition for allowance for at least the reasons set forth hereinabove with respect to claims 1-4, 7-10, 58, 60, 69, and 71. As such, applicants respectfully submit that claims 1-4, 7-10, 58, 60, 69, and 71-75 are believed to be in condition for allowance, and respectfully solicit a Notice of Allowance to that effect.

#### CONCLUSIONS

Should there be any minor issues outstanding in this matter, the Examiner is respectfully requested to telephone the undersigned attorney. Early passage of the subject application to issue is earnestly solicited.

Application Serial No.: 10/541,947


DEPOSIT ACCOUNT

The Commissioner is hereby authorized to charge any fees associated with the filing of this correspondence to Deposit Account Number **50-0426**.

Respectfully submitted,

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